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| **Depression - Adult** |
| **Protocol Id:** | 120502 |
| **Description of Protocol** | This protocol is divided into two parts. Part I consists of the depression section from the Composite International Diagnostic Interview - Short Form (CIDI-SF), developed for the World Health Organization, and is a screening tool for the general population. Part II consists of the Quick Inventory of Depressive Symptoms (QIDS) that captures the severity of depressive symptoms in the last seven days. |
| **Specific Instructions** | The screening protocol included in Part I should be completed on all participants. Part II should be completed on participants that screen positively for depression to provide additional specificity about underlying symptoms.The Psychiatric Working Group has recommended that the portions of the Composite International Diagnostic Interview - Short Form (CIDI-SF) be used separately to screen for specific disorders in the PhenX Toolkit. Specifically, the entire instrument is included as the PhenX Measure General Psychiatric Assessment, section A is included as a protocol for the PhenX Measure of Depression, section I is included as a protocol for the PhenX Measure of Obsessive Compulsive Disorders, and sections B, C, D, E and F are included as a protocol Anxiety Disorders. Therefore, selecting the General Psychiatric Assessment measure in combination with Depression, Obsessive Compulsive Disorder and / or Anxiety Disorders will result in selecting the same protocol multiple times. Contained in these instruments are questions about thoughts of suicide. If using these protocols, please inform your Institutional Review Boards of these questions and institute a plan of action for dealing with suicidal thoughts in your respondent. It may be necessary to create a separate protocol for immediate action and/or referral.  |
| **Protocol:** | Part I: Depression Screener from the Composite International Diagnostic Interview - Short Form1a. Have you ever had a time in your life when you felt sad, blue, or depressed for two weeks or more in a row?1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not Asked1b. Have you ever had a time in your life lasting two weeks or more when you lost interest in most things like hobbies, work, or activities that usually give you pleasure? 1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not AskedIF NO or skip to 1a AND 1b, protocol is done. If YES to either of the two, continue to 1c.Please think of the two-week period in your life when your feelings of depression or loss of interest were worst:1c. How much of the day did these feeling usually last? 1 [ ] All day long2 [ ] Most of the day3 [ ] About half of the day [protocol is complete]4 [ ] Less than half of the day [protocol is complete]-1 [ ] Refused-2 [ ] Not Asked1d. Did you feel this way: 1 [ ] Every day2 [ ] Almost every day3 [ ] Less often [protocol is complete]-1 [ ] Refused-2 [ ] Not Asked2. Did you feel more tired out or low on energy than is usual for you? 1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not Asked3. Did you gain or lose weight without trying, or did you stay about the same weight? 1 [ ] Gained [go to 3aa]2 [ ] Lost [go to 3ab]3 [ ] Both gained and lost weight [go to 3ac]4 [ ] Stayed about the same or on a diet [go to 4]-1 [ ] Refused-2 [ ] Not Asked3aa. About how much weight did you gain? \_\_\_\_\_\_\_\_\_\_ pounds3ab. About how much weight did you lose? \_\_\_\_\_\_\_\_\_\_ pounds3ac. About how much weight did you gain and lose? Gained \_\_\_\_\_\_\_\_\_\_ pounds Lost \_\_\_\_\_\_\_\_\_\_ pounds 4. Did you have more trouble falling asleep than you usually do? 1 [ ] Yes [go to 4A]2 [ ] No [go to 5]-1 [ ] Refused-2 [ ] Not Asked[If skip, go to 5]4a. How often did that happen? 1 [ ] Every night2 [ ] Nearly every night3 [ ] Less often-1 [ ] Refused-2 [ ] Not Asked5. Did you have a lot more trouble concentrating than usual? 1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not Asked6. People sometimes feel down on themselves, no good, or worthless. Did you feel this way? 1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not Asked7. Did you think a lot about death - either your own, someone else’s, or death in general? 1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not AskedPlease again think of the two-week period in your life when your feelings of depression or loss of interest were worst:8. About how many weeks altogether did you feel this way? Count the weeks before, during and after the worst two weeks. The total period of depression/loss of interest was: \_\_\_\_\_\_\_\_\_\_ weeks8a. How many periods like this did you have in your life, lasting two or more weeks? \_\_\_\_\_\_\_\_\_\_ periods8b. About how old were you the FIRST time you had a period of two weeks like this? (Whether or not you received any help for it.) \_\_\_\_\_\_\_\_\_\_ years of age when you first felt this way8c. About how old were you the LAST time you had a period of two weeks like this? (Whether or not you received any help for it.) \_\_\_\_\_\_\_\_\_\_ years of age when the most recent episode happened8d. Did you ever tell a professional about these problems (medical doctor, psychologist, social worker, counselor, nurse, clergy, or other helping professional)? 1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not Asked8e. Did you take medication or use drugs or alcohol more than once for these problems? 1 [ ] Yes2 [ ] No-1 [ ] Refused-2 [ ] Not Asked8f. How much did these problems interfere with your life or activities: 1 [ ] A lot2 [ ] Some3 [ ] A little4 [ ] Not at all-1 [ ] Refused-2 [ ] Not AskedPart II: Depression Symptom Assessment from the Quick Inventory of Depressive Symptoms (QIDS)Please indicate the one response to each item that best describes you for the past seven days.1. Falling Asleep:0 [ ] I never take longer than 30 minutes to fall asleep.1 [ ] I take at least 30 minutes to fall asleep, less than half the time.2 [ ] I take at least 30 minutes to fall asleep, more than half the time.3 [ ] I take more than 60 minutes to fall asleep, more than half the time.2. Sleep During the Night:0 [ ] I do not wake up at night.1 [ ] I have a restless, light sleep with a few brief awakenings each night.2 [ ] I wake up at least once a night, but I go back to sleep easily.3 [ ] I awaken more than once a night and stay awake for 20 minutes or more, more than half the time.3. Waking Up Too Early:0 [ ] Most of the time, I awaken no more than 30 minutes before I need to get up.1 [ ] More than half the time, I awaken more than 30 minutes before I need to get up.2 [ ] I almost always awaken at least one hour or so before I need to, but I go back to sleep eventually.3 [ ] I awaken at least one hour before I need to, and can’t go back to sleep.4. Sleeping Too Much:0 [ ] I sleep no longer than 7-8 hours/night, without napping during the day.1 [ ] I sleep no longer than 10 hours in a 24-hour period including naps.2 [ ] I sleep no longer than 12 hours in a 24-hour period including naps.3 [ ] I sleep longer than 12 hours in a 24-hour period including naps.5. Feeling Sad:0 [ ] I do not feel sad1 [ ] I feel sad less than half the time.2 [ ] I feel sad more than half the time.3 [ ] I feel sad nearly all of the time.6. Decreased Appetite:0 [ ] There is no change in my usual appetite.1 [ ] I eat somewhat less often or lesser amounts of food than usual.2 [ ] I eat much less than usual and only with personal effort.3 [ ] - I rarely eat within a 24-hour period, and only with extreme personal effort or when others persuade me to eat.7. Increased Appetite:0 [ ] There is no change from my usual appetite.1 [ ] I feel a need to eat more frequently than usual.2 [ ] I regularly eat more often and/or greater amounts of food than usual.3 [ ] I feel driven to overeat both at mealtime and between meals.8. Decreased Weight (Within the Last Two Weeks):0 [ ] I have not had a change in my weight.1 [ ] I feel as if I’ve had a slight weight loss.2 [ ] I have lost 2 pounds or more.3 [ ] I have lost 5 pounds or more.9. Increased Weight (Within the Last Two Weeks):0 [ ] I have not had a change in my weight.1 [ ] I feel as if I’ve had a slight weight gain.2 [ ] I have gained 2 pounds or more.3 [ ] I have gained 5 pounds or more.Enter the highest score on any 1 of the 4 appetite/weight change items (6-9 above) \_\_\_\_10. Concentration/Decision Making:0 [ ] There is no change in my usual capacity to concentrate or make decisions.1 [ ] I occasionally feel indecisive or find that my attention wanders.2 [ ] Most of the time, I struggle to focus my attention or to make decisions.3 [ ] I cannot concentrate well enough to read or cannot make even minor decisions.11. View of Myself:0 [ ] I see myself as equally worthwhile and deserving as other people.1 [ ] I am more self-blaming than usual.2 [ ] I largely believe that I cause problems for others.3 [ ] I think almost constantly about major and minor defects in myself.12. Thoughts of Death or Suicide:0 [ ] I do not think of suicide or death.1 [ ] I feel that life is empty or wonder if it’s worth living.2 [ ] I think of suicide or death several times a week for several minutes.3 [ ] I think of suicide or death several times a day in some detail, or I have made specific plans for suicide or have actually tried to take my life.13. General Interest:0 [ ] There is no change from usual in how interested I am in other people or activities.1 [ ] I notice that I am less interested in people or activities.2 [ ] I find I have interest in only one or two of my formerly pursued activities.3 [ ] I have virtually no interest in formerly pursued activities.14. Energy Level:0 [ ] There is no change in my usual level of energy.1 [ ] I get tired more easily than usual.2 [ ] I have to make a big effort to start or finish my usual daily activities (for example, shopping, homework, cooking or going to work).3 [ ] I really cannot carry out most of my usual daily activities because I just don’t have the energy.15. Feeling Slowed Down:0 [ ] I think, speak, and move at my usual rate of speed.1 [ ] I find that my thinking is slowed down or my voice sounds dull or flat2 [ ] It takes me several seconds to respond to most questions and I’m sure my thinking is slowed.3 [ ] I am often unable to respond to questions without extreme effort.16. Feeling Restless:0 [ ] I do not feel restless.1 [ ] I’m often fidgety, wringing my hands, or need to shift how I am sitting.2 [ ] I have impulses to move about and am quite restless.3 [ ] At times, I am unable to stay seated and need to pace around. |
| **Selection Rationale** | The Composite International Diagnostic Interview - Short Form (CIDI-SF) was selected to screen a general populations for the presence of depression because it has been used on thousands of subjects in the US and around the world, is available in multiple formats, is easily administered by trained non-clinician interviewers, is well validated and provides screening criteria consistent with the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) and Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV).The Quick Inventory of Depressive Symptoms (QIDS) was selected to provide additional specificity about the underlying symptoms of those participants that screen positively for depression. The Quick Inventory of Depressive Symptoms (QIDS) was vetted against several other dimensional measures for depression and ultimately selected because it is free, easily administered as a self-reported instrument for ages 12 and above and captures the general symptoms of depression. |
| **Source** | Composite International Diagnostic Index - Short Form: Kessler, R. C., Andrews, G., Mroczek, D., Ustun, T. B., & Wittchen, H-U. (1998). The World Health Organization Composite International Diagnostic Interview Short Form (CIDI-SF). *International Journal of Methods in Psychiatric Research*, *7*(4), 171-185.Quick Inventory of Depressive Symptoms:Rush, A. J , Trivedi, M. H., Ibrahim, H. M., Carmody, T. J., Arnow, B., Klein, D. N., Markowitz, J. C., Ninan, P. T., Kornstein, S., Manber, R., Thase, M. E., Kocsis, J. H., & Keller, M. B. (2003).The 16-item Quick Inventory of Depressive Symptomatology (QIDS) Clinician Rating (QIDS-C) and Self- Report (QIDS-SR): A psychometric evaluation in patients with chronic major depression. *Biological Psychiatry*, *54*, 573-583. |
| **Language** | Arabic, Dutch, English, French, Hindi, Italian, Kannada, Korean, Mandarin Chinese, Marathi, Punjabi, Russian, Spanish, Tamil, Telugu, Turkish |
| **Participant** | The Composite International Diagnostic Index - Short Form can be used for adults age 18 or older.The Quick Inventory of Depressive Symptoms can be used as a self report for age 12 through adult. |
| **Personnel and Training Required** | Composite International Diagnostic Index - Short Form:The interviewer must be trained to conduct personal interviews with individuals from the general population. The interviewer must be trained and found to be competent (i.e., tested by an expert) at the completion of personal interviews\*. The interviewer should be trained to prompt respondents further if a "don't know" response is provided.\* There are multiple modes to administer this question (e.g., pencil and paper and computer-assisted interviews).Quick Inventory of Depressive Symptoms:No training or personnel required for self-administered questionnaire. |
| **Equipment Needs** | While the source protocol for the Composite International Diagnostic Index - Short Form was developed to be administered by a computer-assisted instrument, the PhenX Psychiatric Working Group acknowledges these questions can be administered in a non-computerized format (i.e. pencil and paper instrument). Computer software is necessary to develop computer-assisted instruments. The interviewer will require a laptop computer/handheld computer to administer a computer-assisted questionnaire.Quick Inventory of Depressive SymptomsNo equipment is necessary for a self-administered questionnaire. |
| **Standards:** |

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| **Standard** | **Name** | **ID** | **Source** |
| Common Data Element (CDE) | Child Depression Assessment Score | 3075442 | [CDE Browser](https://cdebrowser.nci.nih.gov/CDEBrowser/search?elementDetails=9&FirstTimer=0&PageId=ElementDetailsGroup&publicId=3075442&version=1.0) |
| Logical Observation Identifiers Names and Codes (LOINC) | Depression adult proto | 62724-0 | [LOINC](http://s.details.loinc.org/LOINC/62724-0.html?sections=Web) |

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| **General references** | American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders: DSM-IV-TR*. Washington, DC: Author.Trivedi, M.H., Rush, A.J., Crismon, M.L., Kashner, T.M., Toprac, M.G., Carmody, T.J., Key, T., Biggs, M.M., Shores-Wilson, K, Whitte, B., Suppes, T., Miller, A.L., Altshuler, K.Z., and Shon, S.P. (2004) Clinical results for the patient with major depressive disorder in the Texas Medication Algorithm Project. Archives of General Psychiatry, 61:669-679.Nelson, C. B., Kessler, R. C., & Mroczek, D. (Aug 2001). Scoring the World Health Organization's Composite International Diagnostic Interview Short Form. (CIDI -SF V1.0 Nov 1998). |
| **Protocol Type** | Self-administered or interviewer-administered questionnaire |
| **Derived Variables** | None |
| **Requirements** |

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| **Requirement Category** | **Required** |
| Major equipmentThis measure requires a specialized measurement device that may not be readily available in every setting where genome wide association studies are being conducted. Examples of specialized equipment are DEXA, Echocardiography, and Spirometry | No |
| Specialized trainingThis measure requires staff training in the protocol methodology and/or in the conduct of the data analysis. | No |
| Specialized requirements for biospecimen collectionThis protocol requires that blood, urine, etc. be collected from the study participants. | No |
| Average time of greater than 15 minutes in an unaffected individualAverage time of greater than 15 minutes in an unaffected individual | No |

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| **Process and Review:** | The Expert Review Panel has not reviewed this measure yet. |